APR 3 0 2002

CARDIOCOMM SOLUTIONS INC™

K020366 p.1/2

Submitter

Name: CardioComm Solutions Inc.
Address: 201 – 3060 Cedar Hill Road
Victoria, B.C., Canada
V8T 3J5
Phone: (250) 744-1822
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Contact: Angela Halwas

Date: January 30, 2002

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K982384.

Device

Name: Global ECG Management System II (GEMS)

Substantial Equivalence is claimed to: Brentwood PC-ECG (K955023)

Description:

GEMS is a software product designed for Microsoft Windows 98, Windows NT, and Windows 2000 operating systems running on an IBM compatible platform. GEMS is compatible with industry standard client server database management systems and as such will operate standalone or on a local or wide area networks. GEMS consists of a user interface that enables health care professionals to input, store, and output data from a relational database.

The product consists of a set of modules that can be installed as required to customize the application to individual users' needs. Modular design has the benefit of encapsulating changes within the overall application. If a module changes, then in most cases the change will affect only that module and will not affect the rest of the program. This permits more efficient and controlled development and testing, and prevents new and unknown safety issues and anomalies from being introduced. This stability contributes to the safety and reliability of the product.

GEMS is capable of multi-tasking and supports the linking and embedding of related information objects in the ECG. The software stores all aspects of a patient's cardiology record including: arrhythmia diagnosis, pathological

diagnosis, ECGs, ECG information, physician notes, clinical history, pacemaker/ICD data and associated reports.

Data can be entered via keyboard, mouse, bar code reader, serial port, or IrDA port, and stored to and retrieved from any computer media. Information can be displayed on the computer monitor or printed.

GEMS is not a life-supporting or life-sustaining system. It is intended that competent human intervention be involved before any impact on health occurs. Clinical judgment and experience are used to check and interpret the data.

Intended Use:

GEMS is intended to be used as a data management tool for cardiologists, general practitioners, cardiac or ECG technicians, nurses, monitoring service technicians, and other cardiac related institutions or care givers to store, retrieve, communicate and report ECG and ECG data acquired from a variety of ECG sources including single and multi-lead ECG devices, including diagnostic 12-lead devices. Users will be able to purchase specific modules for managing other patient cardiac related data such as pacemaker and rehabilitation data that fit their patients' needs. The ECG module may be licensed to other software developers as an ECG viewer for their products. GEMS is intended for use in clinics, hospitals, physician's offices, or anywhere a medical doctor deems appropriate. GEMS does not offer diagnosis or medical alarms. It is intended that competent human intervention be involved before any impact on health occurs. Clinical judgment and experience are used to check and interpret the data.

Technological Characteristics:

Only one feature of GEMS cannot be found in the predicate device: heart rate calculation in software. Testing for calculation of heart rate in software has been completed and submitted according to the relevant sections of AAMI EC38.

All other features of GEMS are present in the predicate. GEMS is therefore substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 3 0 2002

Ms. Angela Halwas
Quality System Manager
CardioComm Solutions, Inc.
201 - 3060 Cedar Hill Road
Victoria, B.C., Canada
V8T 3J5

Re: K020366
Trade Name: Global ECG Management System II (GEMS)
Regulation Name: Electrocardiograph
Regulation Number: 21 CFR 870.2340
Regulatory Class: Class II (two)
Product Code: 74 DPS
Dated: January 31, 2002
Received: February 4, 2002

Dear Ms. Halwas:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

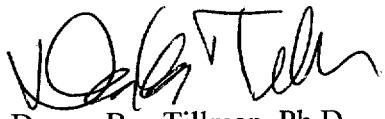
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Donna-Bea Tillman, Ph.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K020368

Device Name: Global ECG Management System (GEMS)

Indications For Use:

GEMS is intended to be used as a data management tool for cardiologists, general practitioners, cardiac or ECG technicians, nurses, monitoring service technicians, and other cardiac related institutions or care givers to store, retrieve, communicate and report ECG and ECG data acquired from a variety of ECG sources including single and multi-lead ECG devices, including diagnostic 12-lead devices. Users will be able to purchase specific modules for managing other patient cardiac related data such as pacemaker and rehabilitation data that fit their patients' needs. The ECG module may be licensed to other software developers as an ECG viewer for their products. GEMS is intended for use in clinics, hospitals, physician's offices, or anywhere a medical doctor deems appropriate. GEMS does not offer diagnosis or medical alarms. It is intended that competent human intervention be involved before any impact on health occurs. Clinical judgment and experience are used to check and interpret the data.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K020368

(Optional Format 3-10-98)

Prescription Use X
(Per 21 CFR 801.109)